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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,586	04/21/2004	Donald L. Kramer	122,046-Div.	5558
23397	7590	08/20/2004	EXAMINER	
BECKMAN COULTER, INC. P.O. BOX 169015 MAIL CODE 32-A02 MIAMI, FL 33116-9015			WALLENHORST, MAUREEN	
		ART UNIT	PAPER NUMBER	
		1743		

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/828,586	KRAMER, DONALD L. <i>(Signature)</i>
	Examiner	Art Unit
	Maureen M. Wallenhorst	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/04 & 7/29/04</u> . | 6) <input type="checkbox"/> Other: _____. |

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1. The disclosure is objected to because of the following informalities: On page 1 of the specification in paragraph no. 001 ("Related US Application Data"), the status of the parent application should be updated by inserting the following phrase after the phrase "US Application no. 10/227,010 filed August 23, 2002": --, now US Patent no. 6,743,634, issued June 1, 2004--.

Appropriate correction is required.

2. Claims 6 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, the phrases "the anticipated location" and "the light-scattering source" lack antecedent basis.

Claim 14 is indefinite and incomplete since it is unclear where in the apparatus of claim 1 that the means for diffusing is located. Is the means for diffusing part of the optical detector? Structural cooperation between the means for diffusing and the other recited components of the apparatus is missing.

Claim 15 is indefinite since it is not clear how the diffused radiation is prevented from being detected by the first and second detectors when claim 15 recites that the diffusing means is located within the bore hole that makes up the second detector itself.

On line 11 of claim 16, the phrase "respective light-collecting" should be changed to – respective light-collecting end--.

In part (e) of claim 18, the second electrical signal lacks antecedent basis since part (d) of claim 18 fails to positively recite a second electrical signal obtained from the second detector.

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Figdor et al (US Patent no. 4,939,081, submitted in the Information Disclosure Statement (IDS) filed on July 27, 2004) in view of Rodriguez et al (US Patent no. 5,125,737, also submitted in the IDS filed July 27, 2004).

Figdor et al teach of a method for separating cells in a blood sample and then analyzing the cells in order to differentiate them from one another. After the cells are separated from a blood sample, the cells are flowed to a cuvette 7 where they are focused so that each cell is separately irradiated by a light beam 8. The light scattered by the cells is then detected using three detectors 13, 14 and 15. Detector 13 serves to detect forward scattered light by the cells, which gives direct information concerning the size of the cells. Detector 14 serves to detect back-scattered light by the cells, which gives information concerning the density of the core of

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the cells. Detector 15 serves to detect side scattered light by the cells, which gives information concerning the internal structure of the cells. Figdor et al teach that the intensity of the scattered light is measured multi-directionally (i.e. forward scatter, back scatter and side scatter) and simultaneously so that data concerning the degree to which cells having specific properties corresponding to each of the directions to be measured, become available during the separation and analysis process. Each of these directions provides data concerning a particular property of the cells. Electronic signals corresponding to each of the scattered light intensities are formed and evaluated by a data-acquisition system in order to differentiate subpopulations of cells in the blood sample analyzed. See columns 2 and 3 in Figdor et al. Figdor et al fail to teach that the cells can also be differentiated by measuring axial light loss or an electrical change caused by the cells passing through the flow cell containing an electrical current therein.

Rodriguez et al teach of a method and apparatus for analyzing cells in a whole blood sample. In the method and apparatus, a sample of blood cells is passed through a cell-interrogation zone which contains therein a transducer for simultaneously measuring the DC volume, RF conductivity, axial light loss, light scattering in the side and forward directions and fluorescence characteristics of the blood cells. The transducer serves as both an electrical and an optical flow cell. Rodriguez et al teach that red blood cells, platelets and white blood cells can be differentiated from one another by obtaining and analyzing the signals from the DC volume, RF conductivity, light scattering in the side and forward directions and fluorescence measurements.

Based upon a combination of Figdor et al and Rodriguez et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to measure the axial

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light loss and DC impedance change caused by the cells in the method and apparatus taught by Figdor et al in addition to the measurements of forward, side and back-scattered light since Rodriguez et al teach that axial light loss and DC impedance can also be used for cell differentiation in a flow cell analysis apparatus, and the method taught by Figdor et al is for the purpose of differentiating blood cells.

6. Claims 1-10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figdor et al in view of Gravitt, Jr. (US Patent no. 3,835,315). For a teaching of Figdor et al, see previous paragraphs in this Office action. Figdor et al fail to teach that the light detectors 13, 14 and 15 contain a plurality of optical fibers in a holder for collecting the scattered light.

Gravitt, Jr teaches of a system for determining parameters of particles by radiant energy scattering techniques that comprises a beam of light 9 provided by a laser 10 directed onto a sample 16. After passing through the sample 16, the beam of light enters into a hole 20 of a fiber optic holder 17 positioned to detect scattered light from the particles in the sample. The holder 17 contains optical fibers 30, 31 in annular rings. The optical fibers 30, 31 are supported in the holder so that their respective axes converge at the point at which the particles in the sample are irradiated. See Figures 3 and 5. The optical fibers contain light collecting ends 25, 26 and light discharge ends through member 18 that direct scattered light to detectors in the form of photomultiplier tubes 32 and 33. See lines 26-52 in column 3 of Gravitt, Jr.

Based upon the combination of Figdor et al and Gravitt, Jr, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a plurality of optical fibers for collecting the light scattered in the forward, side and back directions in the method and apparatus taught by Figdor et al since Gravitt, Jr. teaches that a plurality of optical fibers in a

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flow-through particle analyzer allows one to collect light at more angles, thus yielding more information about the cells.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figidor et al in view of Gravitt, Jr. as applied to claims 1-10 and 16 above, and further in view of Rodriguez et al. For a teaching of Figidor et al, Gravitt, Jr and Rodriguez e al, see previous paragraphs in this Office action. Figidor et al fail to teach that the cells can also be differentiated by measuring axial light loss or an electrical change caused by the cells passing through the flow cell containing an electrical current therein.

Based upon a combination of Figidor et al, Gravitt, Jr. and Rodriguez et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to measure the axial light loss and DC impedance change caused by the cells in the method and apparatus taught by Figidor et al in addition to the measurements of forward, side and back-scattered light since Rodriguez et al teach that axial light loss and DC impedance can also be used for cell differentiation in a flow cell analysis apparatus, and the method taught by Figidor et al is for the purpose of differentiating blood cells.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Figidor et al in view of Gravitt, Jr as applied to claims 1-10 and 16 above, and further in view of Bohmer (US Patent no. 4,702,598, submitted in the IDS filed July 27, 2004). For a teaching of Figidor et al and Gravitt, Jr, see previous paragraphs in this Office action. Gravitt, Jr fails to teach that the fiber optic holder comprises a fiber retaining plate having a concave surface through which a plurality of bore holes are formed in the plate for supporting the fibers.

Bohmer teaches of a flow cytometer for determining the properties of single cells and particles, wherein a stream of particles is passed through a zone of analysis where a light source directs a beam of light to perpendicularly intersect the stream of particles so that only a single cell is exposed to the light beam. An array of optical fibers collects light scattered by the cells as each cell passes through the zone of analysis. Each optical fiber is connected to a photomultiplier for converting the light to an electronic signal. The angles at which the light is collected by the optical fibers is adjustable to permit more light to be collected from more directions to yield more information about the cells. The array of optical fibers is supported in a holder that has a spherical form with a concave surface through which a plurality of bore holes are formed for supporting the fibers. See figures 4 and 6 in Bohmer.

Based upon the combination of Figidor et al, Gravitt, Jr and Bohmer, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a plurality of optical fibers for collecting the light scattered in the forward, side and back directions in the method and apparatus taught by Figidor et al for the reasons given above in paragraph no. 6, and to provide the plurality of optical fibers in a holder having a concave surface with a plurality of bore holes therein, such as the optical fiber holder taught by Bohmer, since the optical fiber holder taught by Bohmer allows scattered light in every possible angle to be measured, thus yielding a strong signal for the particles.

9. Claims 14-15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a flow-through particle analyzer having a flow cell, a light source for irradiating

particles in the flow cell and an optical detector in the form of a plurality of optical fibers in a holder for detecting light back scattered by the particles in the flow cell, which also includes therein an elongated bore hole through which the beam of radiation passes after irradiating the particles in the flow cell so as to become diffused to prevent any diffused radiation from being detected by the optical detector.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Jarofski and DeThomas et al who teach of optical detectors containing a plurality of optical fibers in a holder; and Kramer, which corresponds to the parent application upon which this application claims priority.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 19, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1700~~ 1700